510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
K041273

B. Purpose for Submission:
New Device

C. Analyte:
Human Chorionic Gonadotropin (hCG)

D. Type of Test:
Qualitative

E. Applicant:
WHPM, Inc.

F. Proprietary and Established Names:
WHPM One-Step Pregnancy Test

G. Regulatory Information:

1. Regulation section:
   21 CFR 862.1155
2. Classification:
   Class II
3. Product Code:
   LCX
4. Panel:
   75

H. Intended Use:

1. Intended use(s):
   The One-Step Pregnancy Test is a test for the qualitative determination of human chorionic gonadotropin (hCG) in urine, for the early detection of pregnancy. For over-the-counter use.
2. Indication(s) for use:
   The One-Step Pregnancy Test is a test for the qualitative determination of human chorionic gonadotropin (hCG) in urine, for the early detection of pregnancy. For over-the-counter use.
3. Special condition for use statement(s):
   This is intended for over-the-counter (OTC) sales to lay consumers.
4. Special instrument Requirements:
   Not Applicable

I. Device Description:
The One-Step Pregnancy Test will be sold in three formats: cassette, test strip, and midstream. The test strip and midstream kits consist of one test device sealed in a foil pouch and a package insert. The cassette kit consists of a sealed foil pouch containing one test device and a disposable plastic dropper, and a package insert. Each test device contains goat polyclonal anti-hCG coated membrane and a pad containing mouse monoclonal antibody (anti-hCG) dye conjugate.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   One-Step Pregnancy Test
2. Predicate K number(s):
   K031271
3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Intended Use	• Qualitative determination of hCG in urine for early detection of pregnancy	• Qualitative determination of hCG in urine for early detection of pregnancy
Principle/Methodology	• Sandwich immunochromatographic assay	• Sandwich immunochromatographic assay
	• Mouse monoclonal and goat polyclonal antibodies	• Mouse monoclonal and goat polyclonal antibodies
	• Cassette, test strip, and midstream formats.	• Cassette, test strip, and midstream formats.
	• Read time: 5 minutes	• Read time: 5 minutes
	• Requires urine addition to the device.	• Requires urine addition to the device.
Sensitivity	• 25 mIU/mL	• 25 mIU/mL

K. Standard/Guidance Document Referenced (if applicable):
Not Applicable

L. Test Principle:
The device is a solid phase, sandwiched immunochromatographic assay..

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. *Precision/Reproducibility:*
   Male urine that tested negative for hCG was spiked with hCG to obtain concentrations of 0, 25, and 100 mIU/mL. Twelve (12) replicates of each sample were tested on all product formats of the One-Step Pregnancy Test, and the results were read at 3 minutes. All samples containing 0 mIU/mL were negative, and all samples containing 25 and 100 mIU/mL were positive.
   b. *Linearity/assay reportable range:*
   N/A
   c. *Traceability (controls, calibrators, or method):*
   WHO 3rd International Standard
   d. *Detection limit:*
   The detection limit of the One-Step Pregnancy Test is 25 mIU/mL. Normal male urine was spiked with 5 different concentrations of

hCG (0, 10, 25, 50, and 100 mIU/mL). Five replicates of each sample were tested. All samples at 25 mIU/mL and above tested positive and all samples at 10 mIU/mL and below tested negative.

e. Analytical specificity:

A male urine specimen was spiked with different concentrations of WHO luteinizing hormone (LH), follicle stimulating hormone (FSH), and thyroid stimulating hormone (TSH) into negative (0 mIU/mL) and positive (25 mIU/mL) samples. Ten replicates (10) of each sample were tested using all product formats of the One-Step Pregnancy Test, and the results were read at 3 minutes. The results demonstrated no cross reaction with LH at 500 mIU/mL, FSH at 2000 mIU/mL, and TSH at 1000 mIU/mL. All samples produced expected results.

Prescription and OTC drugs, and chemical and biological analytes were added to negative (0 mIU/mL) and positive (25 mIU/mL) urine samples. The level of interfering substances was determined to be in excess of what would be excreted after 8 hours by the human kidney. Ten (10) replicates of each sample were tested using all formats of the One-Step Pregnancy Test. The results were read at 3 minutes. None of these substances interfered with the results of the test.

Ten (10) replicates of each negative and positive (25 mIU/mL) urine sample at pH levels ranging from 3.16 to 6.13 were also tested. pH did not interfere with the results.

f. Assay cut-off:

See Detection Limit above.

2. <u>Comparison studies:</u>

a. Method comparison with predicate device:

The performance of the three formats of the One-Step Pregnancy Test was compared to the Stanbio True 20 hCG. The study was performed at three clinics. Urine samples were obtained from women presenting at the clinics requesting a pregnancy test. Samples were random, collected at various times throughout the day. A total of 105 patient samples (19 positives and 86 negatives) were collected and tested on the reference test and the subject device. The One-Step Pregnancy Test (all three formats) demonstrated 100% agreement when compared to the commercially available test.

To demonstrate that the product could be used effectively by untrained consumers, 40 women were asked to collect their urine and perform all formats of the One-Step Pregnancy Test using the instructions in the package insert. The test results were confirmed by a laboratory professional, and the urine samples were run on the Stanbio True 20 hCG test. In all cases the consumer results agreed with the laboratory professional's results.

Additionally, 30 women were recruited and asked to test three blinded samples (0, 50, and 250 mIU/mL) on all test formats. No discrepant results were obtained

b. Matrix comparison:
Not Applicable

3. Clinical studies:
   a. Clinical sensitivity:
   N/A
   b. Clinical specificity:
   N/A
   c. Other clinical supportive data (when a and b are not applicable):
   N/A
4. Clinical cut-off:
   See Detection limit above.
5. Expected values/Reference range:
   The expected values are based on literature and in previous sensitivity studies that demonstrated adequate performance at the cutoff of 25 mIU/mL.

N. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.